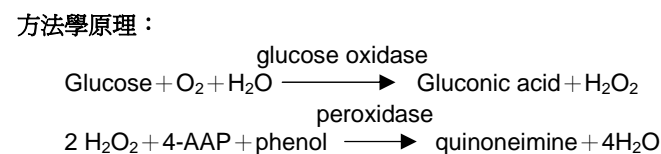




台塑葡萄糖試劑 (GLU-OD) - Enzymatic colorimetric test (GOD-PAP)

效能：
用於臨床實驗體外定量分析人體血清或血漿中葡萄糖的含量。

臨床意義：
血糖濃度受神經系統和激素的調節而保持相對穩定，當這些調節失去原有的相對平衡，則出現病理性的高血糖或低血糖。



- 試劑：**
- 產品規格：
詳見外盒包裝標示。
 - 成份與濃度：

成份	濃度
Buffer pH7.0	
4-Aminoantipyrine	1mmol/L
phenol	10mmol/L
glucose oxidase	36000U/L
peroxidase	12000U/L

保存溫度：
2-8°C 避光保存，請勿冰凍。

檢體：
血清、肝素或 EDTA 抗凝血漿。檢體採集後必須儘快離心處理，或用氟化物抑制酵解作用。

- 操作步驟：**
- 測定主波長：505 nm 測定副波長：660nm
溫度：37°C 比色杯光徑：1.0 cm
 - 本試劑盒為液態單試劑，可直接上機使用。

加入物 (ml)	空白管	標準管	檢體管
檢體 ml	---	---	0.01
標準液 ml	---	0.01	---
去離子水 ml	0.01	---	---
試劑 ml	1.0	1.0	1.0

混勻，於 37 保溫 5 分鐘，以空白管調“零”點，分別在 505nm 及 660nm 處檢測各管吸光值 A， $A = A_{505} - A_{660}$ 。

結果計算

$$\text{葡萄糖 (mg/dL)} = \frac{\text{檢體管吸光值}}{\text{標準管吸光值}} \times \text{葡萄糖標準液濃度 (mg/dL)}$$

參考值：
70-105 mg/dL (3.9-5.8 mmol/L)

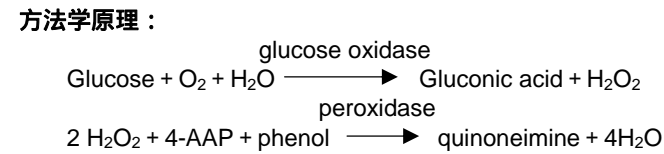
- 注意事項：**
- 本試劑請用專用標準品(calibrator)，不另外提供質控血清(control)，建議質控血清為 Bio-Rad Lyphocek control。
 - 建議各實驗室建立獨立之品管系統，並定義專屬之參考值範圍。
 - 本檢驗試劑限由醫師或醫檢師臨床使用。
 - 為保證結果的準確性，必須在檢體加入後 30 分鐘內檢測吸光值。
 - 本試劑線性可達 400 mg/dL。當檢體的葡萄糖濃度大於 400 mg/dL 時，應將檢體用生理食鹽水稀釋後再分析，結果乘以稀釋倍數。
 - 以上操作步驟適用於手工操作及一般半自動及全自動生化分析儀。
 - 本品操作時需穿戴手套及必要之防護措施，若不慎沾上，應用水或肥皂水清洗。(詳細溶液物化性請洽詢經銷商索取物質安全資料表)
 - 用畢應按醫療事業廢棄物處理。(詳細溶液物化性請洽詢經銷商索取物質安全資料表)
 - 有效期限見試劑盒上標籤所示。
 - 經專業人員建議，試劑與檢體用量可根據所用分析儀的要求按比例調整，其吸光值不變，不影響監測結果。
 - 試劑特性及參數設定請參見第四頁。



台塑葡萄糖试剂 (GLU-OD) - Enzymatic colorimetric test (GOD-PAP)

效能：
用于临床实验体外定量分析人体血清或血浆中葡萄糖的含量。

临床意义：
血糖浓度受神经系统和激素的调节而保持相对稳定，当这些调节失去原有的相对平衡，则出现病理性的高血糖或低血糖。



- 试剂：**
- 产品规格：
详见外盒包装标示。
 - 成份与浓度：

成份	浓度
Buffer pH7.0	
4-Aminoantipyrine	1mmol/L
phenol	10mmol/L
glucose oxidase	36000U/L
peroxidase	12000U/L

保存温度：
2-8°C 避光保存，请勿冰冻。

检体：
血清、肝素或 EDTA 抗凝血漿。检体采集后必须尽快离心处理，或用氟化物抑制酵解作用。

- 操作步骤：**
- 測定主波長：505 nm 測定副波長：660nm
溫度：37°C 比色杯光徑：1.0 cm
 - 本試劑盒為液態單試劑，可直接上機使用。

加入物 (ml)	空白管	標準管	檢體管
檢體 ml	---	---	0.01
標準液 ml	---	0.01	---
去離子水 ml	0.01	---	---
試劑 ml	1.0	1.0	1.0

混勻，于 37 保溫 5 分鐘，以空白管調“零”點，分別在 505nm 及 660nm 處檢測各管吸光值 A， $A = A_{505} - A_{660}$ 。

结果计算

$$\text{葡萄糖 (mg/dL)} = \frac{\text{檢體管吸光值}}{\text{標準管吸光值}} \times \text{葡萄糖標準液濃度 (mg/dL)}$$

参考值：
70-105 mg/dL (3.9-5.8 mmol/L)

- 注意事项：**
- 本试剂请用专用标准品(calibrator)，不另外提供质控血清(control)，建议质控血清为 Bio-Rad Lyphocek control。
 - 建议各实验室建立独立之品管系统，并定义专属之参考值范围。
 - 本检验试剂限由医师或医检师临床使用。
 - 为保证结果的准确性，必须在检体加入后 30 分钟内检测吸光值。
 - 本试剂线性可达 400 mg/dL。当检体的葡萄糖浓度大于 400 mg/dL 时，应将检体用生理食盐水稀释后再分析，结果乘以稀释倍数。
 - 以上操作步骤适用于手工操作及一般半自动及全自动化分析仪。
 - 本品操作时需穿戴手套及必要之防护措施，若不慎沾上，应用水或肥皂水清洗。(详细溶液物化性请洽询经销商索取物质安全数据表)
 - 用毕应按医疗事业废弃物处理。(详细溶液物化性请洽询经销商索取物质安全数据表)
 - 有效期限见试剂盒上标签所示。
 - 经专业人员建议，试剂与检体用量可根据所用分析仪的要求按比例调整，其吸光值不变，不影响监测结果。
 - 试剂特性及参数设定请参见第四页。



MeDiPro GLUCOSE TEST-Oxidase method(GLU-OD) - Enzymatic colorimetric test (GOD-PAP)

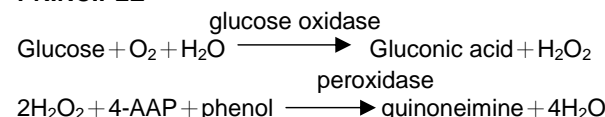
INTENDED USE

For the quantitative determination of glucose in serum or plasma.

CLINICAL SIGNIFICANCE

The most common disease associated with abnormal carbohydrate metabolism is diabetes mellitus, with its accompanying high blood glucose levels. Other conditions which may also result in abnormal blood glucose levels include: disorders of the pituitary gland, hyperthyroidism, Cushing's disease, traumatic injury, convulsive disorders, mental stress and pheochromocytoma. Acute and chronic infection, eclampsia, hypertension and severe liver disease may also exhibit transitory elevation of blood glucose level. On the other hand, hyperinsulinism from either exogenous insulin overdose or from lesions of the pancreas can result in low level of blood glucose.

PRINCIPLE



REAGENT

- Package: please see the reagent box label shown.
- Components:

Component	Conc.
Buffer pH7.0	
4-Aminoantipyrine	1mmol/L
phenol	10mmol/L
glucose oxidase	36000U/L
peroxidase	12000U/L

STORE TEMPERATURE

The standard is stable up to the end of the indicated expiration date. If stored at 2 – 8 °C., reagent should be protected from light and contamination should be avoided. **Do not freeze the reagent!**

SPECIMEN COLLECTION AND PREPARATION

Both serum and plasma samples can be used. For serum samples, collect whole blood and allow it to clot in clean test tube at room temperature. Separate and then transfer the serum without delay to a clean test tube. Do the test as soon as possible or store at 2~8 °C to avoid degradation. For plasma specimens, collect whole blood into a tube containing a suitable anticoagulant, (EDTA, heparin, etc.), separate and transfer the plasma into a clear test tube. To prevent degradation from glycolysis, fluoride (up to 10 mg/dl) may be added with no effect on the test results.

PROCEDURES

- Main wavelength : 505 nm
Sub. wavelength : 660nm
Reaction Temperature : 37°C
Optical path length : 1.0 cm
- This kit contains single reagent, ready to use.

	Blank	Control	Specimen
Specimen(ml)	---	---	0.01
Control(ml)	---	0.01	---
ddH ₂ O(ml)	0.01	---	---
R1(ml)	1.0	1.0	1.0

Mix, incubate at 37°C for 5 min, and read the absorbance against reagent blank. $A = A_{505} - A_{660}$

CALCULATION

With standard or calibrator

$$\text{Glucose (mg/dL)} = \frac{A_{\text{sample}}}{A_{\text{std./cali.}}} \times \text{conc. Std./cali. (mg/dL)}$$

REFERENCE RANGE

70-105 mg/dL (3.9-5.8 mmol/L)

WARNINGS AND PRECAUTIONS

- This kit offers an optional calibrator, which is sold individually. **Bio-Rad Lyphochek control is recommended to use as serum control.**
- Each laboratory has to perform the quality control test to assure the results being reliable before running the specimen tests.
- This kit is for professionals and *in vitro* diagnostic use only.
- To ensure the accuracy of result, the absorbance should be measured within 30 minutes after sample addition.
- The test is developed to determine glucose concentrations up to 400mg/dL. When values exceed this range, samples should be diluted with normal saline and calculate the results by multiplying the dilution factor.
- The above-mentioned procedures are suitable either for the general semi-automatic, full-automatic biochemical analysis instrument or manual operation.
- Since all specimens are potentially infectious, they should be handled with appropriate precautions and practices in accordance with Biosafety level 2 as recommended by USA NIH manual Biosafety in Microbiological and Biomedical Laboratories, and in accordance with National or local regulations related to the safety precautions of such materials.
- Waste management please refers to the local legal requirements.
- Please refer to the manufacturer's safety data sheet and the product labeling for information on



FORMOSA BIOMEDICAL TECHNOLOGY CORP.

F-5F, No. 201, Tunghua N. Rd, Taipei, 105, Taiwan Website: <http://www.fbc.com.tw/>
TEL: +886-2-2712-2211 #7822 FAX: +886-2-2717-8381
Factory: No. 3, Longchuan Rd, Longtang Village, Jiaosi, Yilan County, 262, Taiwan



MeDiPro GLUCOSE TEST-Oxidase method(GLU-OD) - Enzymatic colorimetric test (GOD-PAP)

potentially hazardous components. (MSDS could be obtained from local dealer.)

- According to the technical suggestion, the volume of reagent and specimen could be adjusted in a ratio for full-automatic biochemical analysis instrument use. It won't affect the absorbance and the result.

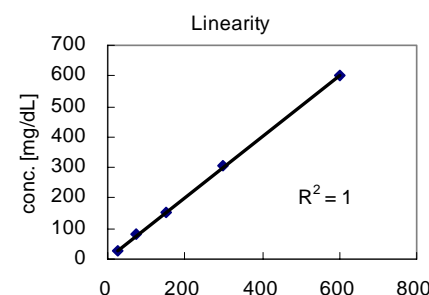
- Validity please see the reagent box label shown.

REAGENT CHARACTERS

- Precision (Within run)

N=15	Mean[mg/dL]	SD [mg/dL]	CV[%]
Sample1	93	0.83	0.90
Sample2	284	2.54	0.89
Sample3	280	2.22	0.79

- Linearity



This kit has a good linearity up to 600mg/dL.

- Interference

Interference	Influence effect
Hemoglobin	No interference was observed by hemoglobin up to 500mg/dL
Ascorbic acid	No interference was observed by ascorbic acid up to 20mg/dL
Bilirubin (free form)	No interference was observed by bilirubin up to 28mg/dL
Bilirubin (conjugate form)	No interference was observed by bilirubin up to 20mg/dL
Intrafat	No interference was observed by intrafat up to 0.2%

- Stability

Expire day	1 year
Open vial stability	30 day

REFERENCE

- Bishop ML, Duben-Engelkirk JL, Fody EP. Clinical Chemistry: principles, procedures, correlations. Fourth edition, 2000.
- Tietz, N.W., Fundamentals of Clinical Chemistry, 2nd. Ed., W.B. Saunders Co., Philadelphia, PA243 (1976).

PARAMETER SETUP

Hitachi 7170 / 917 Applications

TEST	[GLU-OD]
ASSAY CODE	[1 POINT]: [34]-[0]
SAMPLE VOLUME	[2]
R1 VOLUME	[200]
R2 VOLUME	[0]
WAVELENGTH (nm)	[660][505]
CALIB. METHOD	[Linear]

Hitachi 7150 / 717 Applications

TEST	[GLU-OD]
ASSAY CODE	[1 POINT]: [50]-[0]
SAMPLE VOLUME	[3]
R1 VOLUME	[300]
R2 VOLUME	[0]
WAVELENGTH (nm)	[660][505]
CALIB. METHOD	[Linear]

ORDERING INFORMATION

Cat. No.	Product	Package
BC-0019M	MeDiPro GLUCOSE TEST - Oxidase method	R1 6x20ml
BC-0019A	MeDiPro GLUCOSE TEST - Oxidase method	R1 4x60ml
BC-0019B	MeDiPro GLUCOSE TEST - Oxidase method	R1 4x100ml
BC-0019C	MeDiPro GLUCOSE TEST - Oxidase method	R1 4x300ml
BC-0019D	MeDiPro GLUCOSE TEST - Oxidase method	R1 4x500ml



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